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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,686	07/23/2003	Takashi Fujikado	116402	6681

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EXAMINER	
BOCKELMAN, MARK	
ART UNIT	**PAPER NUMBER**
3766	

MAIL DATE	DELIVERY MODE
09/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/624,686	FUJIKADO ET AL.	
	Examiner	Art Unit	
	Mark W. Bockelman	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claim 12 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the reply filed 6-12-2007. In that paper, applicant has stated that the claims (including claim 12) include the limitation that the stimulation electrodes are placed outside the choroid (on a sclera side), and this statement indicates that the invention is different from what is defined in the claim(s) because claim 12 never mentions the relative positioning of the stimulation electrodes relative to the choroid or sclera.

Claims 9, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner questions the meaning of the last clause in each of claims 9, 12 and 13.

Specifically, the last clause in claim 9 includes:

"outputting the converted electrical stimulation pulse signals having a current intensity enough to pass through the choroids and the sclera from the stimulation electrodes to ward the indifferent electrode through an electrical circuit to electrically stimulate the cells constituting the retina from the choroid side"

This language is nowhere to be found in the specification either implicitly or explicitly. Please note the first paragraph rejection that follows. Applicant's disclosure provides for a converter that has a cable extending to an indifferent (reference) electrode inside the eye as well as a cable that extends through the sclera to stimulation electrodes positioned between the sclera and the choroid. Current is said to pass *through the choroid and retinal tissues* from the stimulation electrodes to the reference electrode. Implicitly, current passes *through the converter through each of the cables (electrical circuit) through the sclera to each of the reference and stimulation electrodes*, but no where is a current having an intensity to "**pass through the choroid and the sclera** from the stimulation electrodes toward the indifferent electrode **through an electrical circuit** to electrically stimulate the cells constituting the retina from the choroid side" taught in the original specification. The examiner has no idea what this means or what the intensity value may be for purposes of searching an applying art since it does not make sense in light of applicant's specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the collective teachings of WO/56393, Nisch et al USPN 6,847,847, Suanging et al USPN 7,003,355 (priority to 11- 20-2001) and optionally Chow et al 6,427,087 and/or Taasicker USPN 2,760,483.

Applicant's claimed invention amounts to a collection of alternative arrangements, known to the art that yield predictable results

Wo/563393, Figure 3 shows an implanted receiver 322 converter 320, implanted in the temporal region of a patient away from the eye and electrode array 320 inside the eye. The devices are capable of being connected by a cable connected to coil 323) as well as "capable" of being connected by welding etc. Applicant's statement of intended with a cable provides no patentable distinction. In figures 16 b the electrode array is show as a two part member with some electrodes inside the eye and some outside the retina. Applicant states that the electrode array is inserted in a sclerotic flap and an indifferent electrode is inserted in the eye (a single electrode in claim 12) via a piercing of the eye from the outside. Applicant uses "comprising" and thus one of the inner eye electrodes of the reference qualifies as a "single" electrode although others are present. (Optionally, Chow is cited as providing a single reference electrode within the eye) The WO/56393 reference is silent to the method of inserting the electrode components into the eye portions. Nish et al shows a flap created in the sclera as well as portion of the choroid having been pierced. In view of the Nish et al reference, it would have been obvious to placed the electrode array of the WO/56393 reference in a similar manner and to further pierced the retina to insert the inner whereby piercing the choroid and

retina would constitute piercing the eye from the outside. Wo/56393 is also silent to the current intensity used to stimulate the tissue. One of ordinary skill in the art would recognize that in placing reference electrode(s) inside the vitreous and stimulation electrodes outside the choroid, one would use an appropriate current strength to stimulate the retina and underlying cells as desired. It would have also been apparent to those viewing the Suaning reference that the reference electrode may be provided as a separate electrode from the stimulatin electrodes and would necessary be positioned in the eye by piercing the eye in some sort of manner.

Although not required, Tassicker teaches placing the stimulation electrodes between the choroid and the sclera. The examiner includes such since applicant has argued that such a limitation is in the he claim.

In sum, WO/56393 teaches claimed positioning of the receiver and converter members in the body teaches it's advantages to be placed in the fatty tissue behind the eye as well as placing stimulation and reference electrodes subretinally and inside the eye repectively.

Chow is cited as showing the use of a single reference electrode in the eye.

Suaning implicity shows that positioning the stimulation electrodes outside the choroid was an option and that the placement of a reference electrode in the eye with sufficient current to stimulate retina and underlying cells was known. The advantages to such external positioning are apparent.

Tassicker is cited as showing that positioning the stimulation electrodes between the choroid and sclera can be a useful alternative positioning because it simplifies the

procedure. The examiner also contends that one of ordinary skill in the art reading the Tassicker reference would recognize that a huge advantage exists in that no separation of the retinal layer is needed. Detached retinas are something that a physician and/or patient do not want. One would also implicitly recognize that a flap would be created in forming the pocket allowing insertion of the stimulation electrode assembly.

Nisch is cited as showing a flap.

Recent supreme court decisions have somewhat altered the determination of obviousness in concluding that the choosing of various arrangements and configurations of known parts which merely yield predictable results may be grounds for a prima facie showing of obviousness. The examiner considers such to be the case here. Each element recited by applicant has a corresponding arrangement shown in the art and does not alter the operation of the device in any unpredictable manner by the additional modifications of other features.

Claims 9 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over WO/56393 in view of Nisch et al USPN 6,847,847, and further in view of Tassicker USPN 2,760,483 and Suaning et al USPN 7,003,355. Applicant differs from the claims above in 1) reciting that the electrode array is placed between the choroid and the sclera 2) deleting the requirement that the reference electrode be a single electrode 3) place a requirement of the intensity of the current. Tassicker is cited to show applicant's claimed subretinal placement (between choroid and sclera) whereby a detached retina does not result. Suanging is cited as showing that one of ordinary skill in the art would

recognize that one can use the necessary current intensity when stimulating outside the choriod.

Response to Arguments

Applicant's arguments with respect to claims 9, 12-13 have been considered but are moot in view of the new ground(s) of rejection. The examiner takes issue with applicant's statement that the examiner has added Tassicker and merely provide a conclusury statement. The advantages that result from placing the stimulation electrodes between choroid and sclera are apparent. 1) the operation involved for placement is simpler as noted in column 2 line 20-22. 2) There is no retinal separation required, detached retinas create sever problems with vision 3) The placement is useful when the retina is damaged or not easily detached column 1 lines 40-42. The advantages are apparent to one of ordinary skill in the art. Applicant has previous pointed out that Tassicker sees his device functioning less efficiently when placed there but this is because his light sensor is on the same pad. It is well known to alternatively place the light sensor on a camera as in WO/56393. The advantages here are known as well and the use of a external camera as the light sensor as opposed to implanted ones is a well known modification and such a modification would negate the efficiency problem in Tassicker since no extra tissue must be penetrated by the light in order to reach the sensor.. Contrary to applicant's statements that they are different technologies, it is merely a choice. External devices sue to their size can provide better

resolution, internal devices are more easily worn. Other than that, both sense light and convey the signals to implanted electrodes. The operation are very similar.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272 -4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWB

September 3, 2007

MARK BOCKELMAN
PRIMARY EXAMINER